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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,039	11/20/2003	Richard M. Kream		2539

7590 07/06/2006

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,039	KREAM, RICHARD M.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 5/15/06 has been entered into the record.
- B. Claims 1-4 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The specification is objected to since the priority data in the first line of the specification states that the present invention is a DIV of a U.S. Patent. However, the present application is actually a DIV of the U.S. application from which the patent issued. It is suggested that the first line of the specification be amended to recite, for example;

This is a division of U.S. Application No. 10/134,187, filed 4/26/02 (now U.S. Patent No. 6,881,829)

It is also suggested that the phrase "as to which Applicant elected a restriction of the invention as required by an Office Action mailed on 09/23/03" be removed since this is not pertinent to the priority data.

- B. The amendment filed 5/15/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: large sections of text have been added to the specification. See, for example, pages 20-26 and 32-38. It is not known where original support can be found. Specific examples include page 10, wherein the term "epidural" has been added. Furthermore, it appears that the term "SP" has been broadened to "or any peptide" throughout the added text when it appears that.

Applicant is required to cancel the new matter in the reply to this Office Action.

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3. Claims

- A. All claim objections in the Office Action mailed 12/13/05 have been withdraw.
- B. Applicants should label all claims in each Response with the proper status identifiers (37 CFR 1.121 (c)). Note claims 3 and 4 in the Response filed 5/15/06.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 12/13/05. Applicants have cited work by Syvnan et al., Liederer et al, Schiller et al., Portoghese et al., Cascieri and Liang as well as Mantyh et al. and conclude that these references, taken together, provide support for the breadth of the invention. These arguments have been considered, but are not deemed persuasive. The claims recite a method of transporting a “pharmacologically active” peptide. However, all the supporting reference (supra) as well as Applicants’ own specification only teach how to produce a pharmacologically active SP peptide. Applicants have not provided any guidance or working examples of how to link any peptide other than SP while retaining pharmacological activity. Though the specification (as discussed in Applicants’ arguments) teach how to physically construct a capped electrically neutral, linear sequences with the non-peptide opioid covalently bound to “any peptide,” there is no discussion, nor is it predictable, on how to retain the activity of the breadth of “any peptide” claimed. It is believed that all pertinent arguments have been addressed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 12/13/05. Applicants have cited work by Syvnan et al., Liederer et al, Schiller et al., Portoghese et al., Cascieri and Liang as well as Mantyh et al. and conclude that these references, taken together, provide written description for the invention. Since Applicants’ arguments have been grouped in with their arguments for enablement, the Examiner’s response is the same as above.

6. Double Patenting

A. The double patenting rejection over U.S. 6,759,520 has been withdrawn since the claims of the patent are drawn to peptides whereas those of the present invention are drawn to non-peptides.

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B. Claims 1-4 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,881,829 for the reasons already of record on page 5 of the Office Action mailed 12/13/05. Applicants have stated that they have overcome the rejection based on this response to the rejections under 35 USC 112, first paragraph. However, it is still unclear how the present claims differ from the claims of '829.

7. Claim Rejections - 35 USC § 102

A. The rejection under 35 USC 102 over U.S. 6,759,520 has been withdrawn since the claims of the patent are drawn to peptides whereas those of the present invention are drawn to non-peptides.

B. Claims 1-4 remain rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The present invention and U.S. Patent 6,759,520 have one common inventor, Richard Kream. However, the patent and the application are not commonly owned. Applicants did not address this rejection.

8. Claim Rejections - 35 USC § 103

A. The rejection under 35 USC 103 over Wainer in view of Foran has been withdrawn in view of Applicants' arguments that the molecules of the conjugate of the present invention are differently linked than those of the art.

9. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

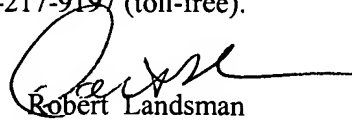
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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Landsman
Primary Examiner
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